510(k) Summary
Safety Biopsy Needle System

General Information

Date Prepared:	January 7, 2014
Submitter Name:	PFM Medical, Inc
Address:	1815 Aston Ave Suite 106 Carlsbad, CA 92008
CONTACT PERSON:	SALVADORE F. PALOMARES, RAC
PHONE NO:	760.758.8749

Device System

Proprietary:	Safety Biopsy Needle System
Common:	Instrument, Biopsy
Classification:	II
Product Code:	FCG
CFR Section:	21 CFR 876.1075

Predicate Devices

Manufacturer:	PROMEX Technologies, LLC (US Biopsy)
Address:	9001 Wesleyan Road Indianapolis, IN 46268
Name:	Full Core Biopsy System
510(k) #	K111765
Manufacturer	VLV Associates, Inc
Address:	30-C Ridgedale East Hanover, NJ 07936
Name:	Promed Biopsy Needle
510(k) #	K933364

Device Description

The Safety Biopsy Needle System consists of two main components: The Safety Biopsy Needle and the Safety Coaxial Needle with Finger Guard.

The Safety Biopsy Needle is composed of two primary assemblies: the biopsy needle and the safety mechanism. The material used to manufacture both the biopsy needle and the safety mechanism is polycarbonate. The needle sheath is made of polyethylene. The available gauges for the safety biopsy needle ranges in size from 14 to 20, with lengths ranging up to 20 centimeters.

The Safety Coaxial Needle with Finger Guard is composed of two primary assemblies, the coaxial needle cannula and the stylet. The material used to manufacture the assembly and introducer cannula, and for trocar stylet, is stainless steel. The needle sheath is made of polyethylene. The available gauges for the safety coaxial needle with finger guard ranges in size from 15 to 19, with lengths ranging up to 17 centimeters.

The Safety Biopsy Needle System is sterilized via Ethylene Oxide (EtO) and is designed for single use only.

Intended Use

The Safety Biopsy Needle System (Safety Biopsy Needle and Safety Coaxial Needle with Finger Guard) is intended to be used for soft tissue and tumor biopsy of such organs as the liver, spleen, kidney, prostate, lung, breast, and lymph nodes.

When used for breast biopsy, the product is for diagnosis only. The extent of histological abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histological abnormality; e.g., malignancy. When sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal of using standard surgical procedures.

Substantial Equivalence

By definition, substantial equivalence means that a device has the same intended use and technical characteristics as the predicate device, or has the same intended use and different technological characteristics, but can be demonstrated to be as safe and effective as the predicate device. The Safety Biopsy Needle System design and technology is substantially equivalent to the basic catheter design and function of the predicate devices (K111765 and K933364). The differences between the Safety Biopsy Needle System and the predicate devices do not raise questions regarding safety and effectiveness of the system. The proposed system, as designed, is as safe and effective as the predicate system.

Performance Testing

Performance testing of the Safety Biopsy Needle System was conducted in accordance with the following international standards:

- Guidance on Premarket Notification [510(k)] for Medical Devices with Sharps Injury Prevention Features; Guidance for Industry and FDA. 03/01/1995
- AAMI/ANSI/ISO 10993-1:2009, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, and the FDA Modified Safety & ISO 10993 Test Profile
- AAMI/ANSI/ISO 1 0993-7:-2008, Biological Evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Results
- AAMI/ANSI/ISO 11135:2007, Sterilization of Healthcare Products Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices ISO 14971:2007, Medical Devices - Risk Management for Medical Devices.

Furthermore, the following non-clinical bench tests were performend on the Safety Biopsy Needle System

- Ability to extract a biopsy tissue sample
- Average Tissue Length
- Edge of Cut Sample Evaluation
- Force to Arm the Safety Biopsy Needle
- Force to Activate the Safety Biopsy Needle
- Multiple Arming-Activation of the Safety Biopsy Needle
- Penetration Force of the Safety Biopsy Needle
- Force to overcome the Anti-Needle Stick Feature Safety Biopsy Needle
- Force to Break Safety Tape Safety Biopsy Needle
- Force to detach Safety Tape from Adapter
- Force to detach Safety Tape from Spool
- Force to peel Safety Tape after being affixed to each other
- Force to advance the Depth Stop on the Safety Coaxial Needle.
- Force to penetrate tissue on the Safety Coaxial Neede.
- Safety Coaxial Needle (SCN) Obstruction Test
- Force to overcome the Anti-Needle Stick Feature Safety Coaxial Needle
- Force to Break Safety Tape Safety Coaxial Needle
- Force to detach Safety Tape from Trocar Hub

- Simulated Clinical Use Evaluation
- Sharps Injury Prevention Evaluation

The biocompatibility tests conducted on the Safety Biopsy Needle System demonstrate that the device meets the requirements of ISO 10993-1:2009.

All of these performance tests demonstrate the device performs according to its intended use and meets the performance specifications.

Summary

Based on the indications for use and safety and performance testing, the Safety Biopsy Needle System meets the requirements that are considered for its intended use and is substantially equivalent in design materials, sterilization, and indications for use. The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 25, 2014

PFM Medical, Inc.
% Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K140137
Trade/Device Name: Safety Biopsy Needle System
Safety Biopsy Needle and Safety Coaxial Needle
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCG
Dated: March 13, 2014
Received: March 14, 2014

Dear Mark Job,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140137

Device Name: Safety Biopsy Needle System
Safety Biopsy Needle and Safety Coaxial Needle

Indications for Use:

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Prescription Use ___X___ AND/OR Over the Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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